# CLINICAL PLACEBO USE: ETHICAL AND UNJUSTIFIED

An Undergraduate Research Scholars Thesis

by

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# ABSTRACT

Clinical Placebo Use: Ethical and Unjustified

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Over the last 60 years, there has been a shift in how the patient-physician relationship is viewed. This shift has resulted in patients having a more active role in the decision-making process in regards to treatments. Modern informed consent requirements seem to demand patients are fully informed in order to offer consent and the absence of deception. An unexpected problem arises when we consider the ethical use of deceptive placebo use in the clinical setting within this modern framework. I wanted to known if there was space within the modern informed consent framework for the lack of information required for effective placebo use, such that the missing information did not constitute deception.

Authors, such as Barnhill and Kolber, often misinterpret the AMA doctrine and hold the policy to establishing a categorical prohibition against deceptive clinical placebo use. I will show that these authors have misread the AMA doctrine, but in doing so, their discussions begin to offer some of the missing justification for the AMA policy.

I will evaluate three dominant stances within the literature and evaluate them in light of four hypothetical cases. In doing so, I will establish that none of the defenses are able to completely justify the AMA view. Accepting this, I believe that Shaw, working within the negative informed consent framework, offers the most robust defense.

# CHAPTER I

# INTRODUCTION

Over the last 60 years, there has been a shift in how the patient-physician relationship is viewed. Patients are now encouraged to take a more active role in the decision-making process in regards to treatments. Following is a brief summary of informed consent. From this, we can begin to see the issues that have arisen as informed consent has evolved over the years.

Informed consent was first defined in a California medical malpractice case (Salgo v. Leland Stanford Jr. University Board of Trustees) in which the plaintiff felt the physician did not properly disclose the risks of the recommended course of treatment. Martin Salgo had an aortography preformed (insertion of contrast through a catheter placed in the femoral artery with X-ray images taken) and awoke paralyzed having never been informed of this potential risk. The judge agreed and a standard for information that must be disclosed in order to obtain informed consent resulted from the decision. The four cornerstones for informed consent outlined were:

1) Risks
2) Alternatives
3) Nature
4) Consequences.

Much of the discussion that followed this case, and is highlighted in the fiduciary model, is the importance of trust between patient and physician. (Salgo 1957) Importantly, informed consent is not a one-time act, but should be a process of honest discussion over the course of treatment. A

clear distinction is made between consent for research and consent for treatment (I will refer to consent for treatment as consent within a clinical setting and clinical placebo as consent for treatment). A 2014 paper out of Australia argues that people are irrational and poor decision makers. Typically, patients are biased to believe they will have a more positive outcome and are myopic. These human tendencies could result in the undermining of informed consent under current guidelines, but could further suggest a shift back to beneficence outweighing autonomy. (Neil 2016) I believe moving backwards may be a step too far. If anything, these human tendencies further illustrate the need of a trusting relationship and partnership in healthcare. Most of the literature objecting placebo use in a clinical setting is based on the tenant of nature.

Further, modern interpretations of patient consent seem to require that patients are fully informed and that there is no deception. An unexpected problem arises when we begin to consider the use of placebo in a clinical setting. Research indicates that in order for the patient to receive the most therapeutic benefit from the placebo, be it a pill or a treatment, the patient must not become aware that they are currently receiving a placebo. However, deceptive placebo use under the modern patient-care model appears to be in direct violation of ethical medical practice. The American Medical Association's (AMA) policy on clinical placebo use is that the practice is ethical, and therefore it must be justified. (AMA 2007) However, the AMA offers no explicit justification for this position. This allows for alternative interpretations of the policy and the debate within the literature begins to offer possible justifications.

Anne Barnhill does an excellent job of outlining the prominent issues and constructing a central autonomy-based argument in her 2011 paper, "What it Takes to Defend Deceptive Placebo Use."

(Barnhill 2011)The central autonomy-based argument puts forth that patients, being unaware of the placebo nature of their treatment, are incapable of giving fully informed consent. This type of autonomy is said to protect the patients' right to choose a treatment. This argument reflects a larger trend within medicine, and even society as a whole. Initially, there were two opposing schools of thought: a "paternalistic model" that held beneficence supreme, in which physicians acted unilaterally, and another, an "autonomy model" that prioritized self-determination or gave the patient ultimate decision-making power. Over time, these schools merged, resulting in the modern mindset of a fiduciary partnership model, a model in which a trusting relationship between the physician and patient is prioritized and informed consent becomes a continual act. (Boyd 2015)

This shift, to a principle of partnership between physician and patient, brings with it a host of questions involving informed consent, the role of each participant and amount and type of information that should be provided. The American Medical Association (AMA) has a policy concerning clinical placebo use that is often held to be a categorical prohibition. For example, Adam Kolber states, "…in November 2006 when the American Medical Association (AMA), the most powerful and influential organization of doctors in the United States, adopted an ethics policy prohibiting the deceptive use of placebos." (Kolber 2007) Anne Barnhill also holds the AMA to a categorical prohibition, "The American Medical Association prohibits physicians from giving placebos to their patients unless the patients are informed of and agree to the use of the placebos. This prohibition…"Authors, such as Barnhill, routinely attempt to soften this position and sometimes work within the patient-autonomy framework. I will limit the following discussion to this class of author.

In what follows, I will show that the AMA position is not a prohibition, much less a categorical one. I will also show that the actual AMA position, while much softer, is left largely unjustified. That is, it is far from clear how the actual policy complies with patient autonomy within the modern informed consent framework. This generates the question: is placebo use under the AMA position justified given patient autonomy? Put another way, is there space within the modern patient autonomy framework, for that there can be the lack of information necessary for effective placebo use, such that this missing information does not constitute deception? While authors, such as Barnhill, put forth a critique of the AMA, their misreading can be best understood as a supplement to the AMA's position. I will argue that while the literature often misinterprets the AMA position, in doing so, these authors are able to broach important issues. Their work begins to provide the much-needed justification for the AMA policy. I will look at three dominant authors in the field as they attempt to soften the AMA position, all the while working within the framework of patient autonomy and evaluate these positions in terms of filling in the lacuna.

First, Barnhill uses carefully constructed definitions to create very narrow limits on what is considered deceptive placebo. Second, Adam Kolber utilizes the dominant ethical framework that informed consent requirements are fulfilled when discussing potential treatments. This allows for patients to choose what role they would like to have in the decision making process, even if that preference is for more limited disclosure. Ulrick Kihlbom (Kilhbom 2008) and David Shaw (Shaw 2009) build upon Kolber's work and will be considered as well. Third, Onora O'Neill (O'Neill 1984) asserts that patients have a limited ability to give autonomous informed

consent and that there must be a realistic burden of disclosure. O'Neill claims that informed consent should be limited to the fundamental aspects of actions only. The case structures of surgical consent, steroid treatment for RA, beneficial side effect case and finally clinical pseudo-placebo will be used to compare the relative strengths of their arguments.

First, let us imagine a case involving surgical consent. Let us imagine that in this case, the patient is not fully informed. That is to say, the patient has not been told, understood and given consent for every possible complication and response the surgical team may be faced with during the operation. The literature will demonstrate that a patient can never truly be fully informed, but rather there exists a more relaxed standard for adequately informed consent. Using a Baylor Scott & White surgical consent form as a representative sample, the patient would have been informed of the basics of the surgical procedure: why it was recommended, the expected benefits and most likely complications or risks. (Baylor Scott & White Health 2014) Allergies to commonly used medications and blood transfusion preferences are recorded. Let us also consider that the patient has not been fully informed. By this I mean, the patient has not been told, does not understand, and has not consented to all of the possible outcomes of the procedure and responses to these outcomes. Has the patient consented to all of the standard responses to those complications down to the types of needles or surgical thread that would be used? Should an issue arise, what are the surgeons to do? Should they stabilize and then wake the patient to seek specific permission before continuing? The aforementioned consent form answers these questions. Specifically, the patient gives permission for their physician, and care team, to respond to unexpected developments with their best professional judgment. Under the AMA policy, this surgical type of consent is actually what is presented. The patient is consenting to a

basket of potential treatments. I believe this may be the AMA's position. "Fully informed" is an unapproachable standard. However, the fact that consenting to an indeterminate basket of potential treatments seems to be the dominant practice does not itself justify the procedure.

Secondly, the consideration of steroid use for the treatment of arthritis patients will be used to adjudicate the dominant stances in the literature. This is the case with the use of steroid treatment to treat autoimmune types of arthritis (such as Rheumatoid). Physicians know that Rheumatoid Arthritis (RA) occurs when the patient's immune system begins attaching itself, and further, physicians know that inflammation in the joints exacerbates the pain and stiffness resulting in decreased mobility. Steroids should address both of these mechanisms by suppressing the overactive immune system and decreasing inflammation. However, the exact mechanism has yet to be isolated and *proven* in a laboratory setting. Let us imagine that in a clinical setting, it is standard protocol to prescribe steroids for RA, and it is not expected for the physicians to detail the complications above. Following is a brief explanation of the types of issues that this hypothetical case gives rise to. First, when explaining the recommended treatment, should the physician be required to explain the specific pharmacological effect to the patients? I will argue that doing so would not serve to increase the patient's understanding of the proposed treatments and risks; and therefore, does not serve to increase informed consent nor does it protect patient autonomy. Secondly, if the patient believes that more detailed information is required for them to make an adequately informed autonomous decision, the physician could provide these details at such a time as the request is made.

The third case used to analyze the dominant stances in the literature is the hypothetical case where one prescription is used to treat multiple conditions. I will refer to this practice as utilizing the beneficial side effects of a primary treatment to treat one, or more, secondary complaints (or beneficial side effects for brevity). This would be the case when, hypothetically, a physician treats a patient's primary complaint with a treatment selected because it has been reported to also alleviate the patient's secondary conditions or complaints. Let us assume that the selected treatment has not undergone separate clinical trials to evaluate their effectiveness at treating the patient's peripheral complaints, but the physician may be aware that patients have previously reported therapeutic benefit. For example, anti-psychotic medications have been reported to decreasing migraine headaches. With neurological treatments, there is an added layer of complexity: many areas of the brain are not very well, let alone completely, understood. One issue that arises here is that the treatment should not be considered a placebo for the primary complaint (the condition the treatment has been approved to treat), but may be considered a placebo treatment for any other peripheral conditions, which the beneficial side effects relieve. If the treatment is then considered partially a placebo, should it be ethical to use? I will show that the literature is divided on this point. Another issue stemming from this hypothetical case is that the physician does not know all of the mechanisms and interactions in play; they cannot be expected to explain to the patient the *specific* mechanism behind its action. As such, leading authors, such as Barnhill, will argue that the patient cannot give fully informed, autonomous consent.

For clarification, the beneficial side effects view is not referring to the case where multiple treatments are prescribed with the intention to treat one disease through multiple pathways. This

is not, for example, the same thing as offering beta-blockers, diuretics, and ACE inhibitors all to treat hypertension. It could be the case that the patient knowing that there is a possibility this treatment may help, but that it is not officially approved for the condition in question is all that should be considered fundamental. Of course, the patient reserves the right to revoke consent at any point. Also of note, if the patient begin experiencing worsening symptoms or did not show acceptable improvement, the physician would then be motivated to revert to the approved protocols and treat the conditions separately.

Finally, pseudo-placebo cases will be considered. By this I mean when a hypothetical case when a physician has a logical reason to believe the treatment will work, patients report therapeutic relief, but there has been no evidence that it does. In some extreme cases, the initial clinical research indicates that, physiologically, nothing is happening. As long as there is no evidence that the treatments could be detrimental, should the patients be denied this treatment option? Kolber argues that they should not be allowed, and Kihlbom and Shaw maintain that pseudo-placebo treatments should be allowed. For clarification, this case is not the same as when an antibiotic medication is offered to a patient suffering from a viral infection. The antibiotic has a known physiological mechanism that has been proven to be effective to safely treat a specific bacterial infection in humans while simultaneously, this same antibiotic would have no antiviral properties.

For the remainder of this discussion, I am limiting my discussion to physicians that act in good faith, devoid of malicious intent, according to best practices, and with respect for the patient's autonomous choices.

# CHAPTER II

# AMA POSITION

## AMA Opinion

Given the apparent tension between placebo seemingly requiring deception and the standard for patient autonomy requiring fully informed consent, how might placebo be used ethically in a clinical setting? Let us consider a test case. In this case, a patient is told that placebos may be used at some point in the course of treatment. The patient agrees to their use; however, the patient is unable to identify which treatments are placebos and the patient is unaware of the precise timing of their use. Is this case ethically permitted?

When we turn to the literature, Anne Barnhill holds a representative view. In her paper, Barnhill states, “The American Medical Association prohibits physicians from giving placebos to their patients unless the patients are informed of and agree to the use of placebos.” Barnhill puts forth that in order to agree, or give consent, a patient must be informed about the placebo nature of the treatment. Therefore, the AMA is held to having a strict prohibition against deceptive placebo use. So what then constitutes deceptive practice? Barnhill defines deception as, “when through words or actions, a physician knowingly causes a patient to believe she’s receiving a drug or treatment that has a specific pharmacological or physiological effect on her condition, when in fact she’s receiving a placebo.” Accordingly, the patient needs to be able to distinguish between the placebo and drugs or treatments that are efficacious.

Commonly, the AMA is quoted as stating, "Physicians may use placebos for diagnosis or treatment only if the patient is informed of and agrees to its use." Leading authors, including Barnhill and Kolber, stop at this sentence. The isolated AMA sentence, when combined with Barnhill's argument, seem to make a strong argument that the aforementioned test case is in conflict and would be considered deceptive. More specifically, the patients being unable to identify the placebo treatment and being unaware of the precise timing of the placebo appears to be in violation of the AMA policy, as it has been represented by Barnhill. Therefore, clinical placebo use should be considered unethical.

Let us now consider the actual policy. When considering placebo specifically, the AMA's current policy is listed under opinion 8.083,

> "A placebo is a substance provided to a patient that the physician believes has no specific pharmacological effect upon the condition being treated. In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient-physician relationship, and result in medical harm to the patient.
>
> **Physicians may use placebos for diagnosis or treatment only if the patient is informed of and agrees to its use. A placebo may still be effective if the patient knows it will be used but cannot identify it and does not know the precise timing of its use.** A physician should enlist the patient's cooperation by explaining that a better understanding of the medical condition could be achieved by evaluating the effects of different medications, including the placebo. **The physician need neither identify the placebo nor seek specific consent before its administration.** In this way, the physician respects the patient's autonomy and fosters a trusting relationship, while the patient still may benefit from the placebo effect.
>
> A placebo must not be given merely to mollify a difficult patient, because doing so serves the convenience of the physician more than it promotes the patient's welfare. Physicians can avoid using a placebo, yet produce a placebo-like effect through the skillful use of reassurance and encouragement. In this way, the physician builds respect and trust, promotes the patient-physician relationship, and improves health outcomes." (emphasis mine).

Commonly, in the literature, by only quoting the first bolded statement, this opinion is held to be a categorical prohibition against clinical placebo use. However, the very next sentence reads, "A placebo may still be effective if the patient knows it will be used but cannot identify it and does

not know the precise timing of its use." The same paragraph continues, "The physician need neither identify the placebo nor seek specific consent before its administration." This is a much softer position than the argued categorical prohibition and reads much differently than Barnhill proposes. If we now reconsider the test case and the unexpected problem with clinical placebo use, the parameters of the test case are the exact sort of thing that the AMA policy is describing that the literature often refers to being deceptive and considered unethical.

What is most notably missing from the opinion is any attempt to justify the ethical use of placebo. Additionally, the definition for placebo is very narrow and there is no mention of "deception." From this opinion, one can gather the importance of a trusting relationship and respect for patient autonomy. Following is the AMA report, which begins to fill in some of the gaps.

**AMA Report**

The AMA opinion is based on the 2008 report, which explains that *deceptive* placebo use is unethical because it does violate notions of patient autonomy and risks losing patients' trust. (Bostick 2008) Patient autonomy is protected, because the patient is able to play an active role in the decision-making process. I will later evaluate how Barnhill uses the same type of logic to build her central autonomy-based objection. The AMA asserts that physicians deceive patients by, "…representing placebos as pharmacologically active medications." Barnhill offers a broader definition for both placebos and deception that are beneficial and will be discussed in Chapter III.

The report goes on to say that physicians can use placebo *without deception* by, "informing the patient that a placebo may be used." However, like in the policy, the exact timing is not required to be known, the patient need not be able to identify the placebo and further no specific permission/consent must be obtained. The report, as well as the policy, concludes that by doing so, "…the physician respects the patient's autonomy and fosters a trusting relationship, while the patient still may benefit from the placebo effect." While this report does give examples of how placebo could be used in a clinical setting without being unethical, it still does not offer any justifications

What is still missing from both the AMA policy and AMA report is any attempt to justify the ethical use of placebo. How then can we resolve placebo use and its inherent deception with the modern patient-autonomy model, which requires fully informed consent absent of deception? It should be noted that there is a difference between the AMA declaring a practice ethical by providing a legal outline of accepted practice and providing justification for why this practice should be considered ethical. Just because there is a policy in place, and it is common practice to follow this policy, does not in itself justify the practice. In what follows, I will evaluate the three dominant stances in the literature with respect to the four example cases.

# CHAPTER III

# BARNHILL JUSTIFICATION

As previously mentioned, Barnhill asserts a much stricter AMA position on placebo, and while I argue that she misinterprets the AMA opinion, in doing so, she begins to fill in the lacuna. Barnhill begins by claiming the AMA holds a categorical prohibition against placebo, and that this stance is beneficial to patients. Barnhill believes placebo use is bad, because the patients, being unaware of the nature of the treatment, cannot consent. This ultimately violates patient autonomy. As her paper continues, Barnhill ultimately settles on a position much closer to the AMA view. In doing so, Barnhill provides some of the missing justification for ethical placebo use.

The AMA defines a placebo as, "a substance that the physician believes has no known specific pharmacological activity against the condition being treated." Barnhill offers a needed and broader definition of placebos, "to not just substances provided to the patient but also procedures- for example, surgery and acupuncture." This is useful because acupuncture (a pseudo-placebo treatment) may not have a pharmacological effect, but has been reported to lessen back pain. Under the AMA definition it would be a placebo, but may not be under Barnhill. Under the AMA definition, even sutures would be defined as a placebo treatment. This expansion of placebo does not provide grounds for the beneficial side effects case, because the standard requires that the specific pharmacological activity may not be in regards to one of the

conditions being treated. Additionally, steroid treatment for RA is also not covered by the more inclusive definition.

Intentionality is important under the AMA definition. While the treatment may not change, the expected or believed effect can cause it to be considered a placebo or an active treatment. Additionally, the AMA requires that a *specific* pharmacological effect must be known. I believe this is impractical and over-restrictive. While it would be disclosed, I have witnessed physicians telling their patients, "We don't know exactly how it works…" or, "The mechanism is yet to be discovered…" or, "Patients have reported excellent outcomes when…" Are these statements sufficient in explaining the lack of medical knowledge, while still providing a defense for their recommendation? Gone are the days of paternalistic practices where physicians had extreme latitude in deciding treatments on the patients' behalf. As societal expectations and perceptions of patient autonomy have changed, there has been a resultant need to analyze the seemingly inherent deception that accompanies clinical placebo use. Unfortunately unlike with placebo, the AMA does not offer any foundation for the definition of deception. Only warnings are issued to avoid the use of deception and example protocols are detailed to support the conclusion that placebo use is not always or inherently deceptive.

However, Barnhill once again provides us with a useful definition, "Deceptive placebo use…is when through words or actions, a physician knowingly causes a patient to believe she's receiving a drug or treatment that has a *specific* pharmacological or physiological effect on her condition, when in fact she is receiving a placebo." Barnhill notes there is a distinction between deception

and lying and that deception occurs when, "the physician knowingly causes the patient to believe something about his treatment… that the physician knows to be false." Following from this definition of deception, Barnhill argues that patients do not know the true nature of the proposed treatment and therefore cannot give informed consent. This is what she calls the central autonomy-based objection, which is designed to protect the patients' ability to choose or control the treatments they receive before treatments are administered. Without knowing the fundamental nature of the placebo treatment being proposed, Barnhill asserts that patients cannot give consent, which on the surface seems to result in these treatments (such as beneficial side effects case and the pseudo-placebo case) being deceptive and unethical. However, the patients would not be receiving a solely placebo treatment. Additionally, the claim for deception occurs when the patient now believes something the physician *knows* to be false. Steroids treatment for RA, beneficial side effects case and pseudo-placebo treatments are not fully understood. Therefore, a physician is not claiming something they *know* to be false. Surgical consent is also justified within this view, because the intended nature of the treatments and the believed method of action could be fully explained to the patient without risk of decreasing their efficacy.

In what appears to be a contradiction, Barnhill later states, "Unless we believe in magic or mind-body dualism, there is a physiological mechanism underlying the effective use of placebos." Therefore, even Barnhill acknowledges that the treatments are not inert, something is happening, the physician just may not know exactly how the benefits are occurring. Whether the placebo is acting in a psychological versus pharmacological way may be considered fundamental, but there is not an explanation as to why this would be. Sutures don't act in either a psychological or pharmacological way and neither do topical or implanted nerve stimulators for pain. Barnhill

uses the example of two different pain medications. When describing the options to a patient, a physician, "…needn't explain the different physiological mechanism whereby each works. She need only explain the risks, benefits and likely outcomes of taking each." Here it would appear that the physician knowing the proposed treatment would work should be considered sufficient for avoiding deception. Given this, we have reason to believe that pseudo-placebo, the beneficial side effects case, and steroid treatment for RA all have grounds for being considered ethical. Following this example, physiological mechanism is not considered a fundamental aspect of treatment, however the nature of a placebo may be considered fundamental. Barnhill's analysis considers the "reasonable patient standard" and the "subjective standard." Both of these standards have a common thread; they depend on what the patient would specifically consider to be relevant to the decision-making process. They are not generalized standards based on statistical averages, and they cannot be determined in a small test group and applied to the world at large. We will observe this limitation throughout the literature.

In summary, Barnhill offers us some conflicting perspectives on all of the four cases except the surgical consent case. Through the expanded definition of placebos to include treatments, Barnhill offers a beginning defense for pseudo-placebo treatments. The proposed definition of deception hinges on the physician intentionally or being aware that they have caused the patient to believe something about the proposed treatment that the *physician knows* to be false. With pseudo-placebo, beneficial side effects case and steroid treatment of RA cases, the physician does not know the method of action, and therefore is incapable causing the patient to believe something *known* to be false. Barnhill further justifies these three cases in her consideration of mind-body dualism and by acknowledging that some patients may not consider the mechanism

of action to be a fundamental, and therefore necessary, piece of information in order to give autonomous informed-consent. However, this determination must be made by each patient individually and is inadequate to be applied as a universal justification for the AMA view.

# CHAPTER IV

# NEGATIVELY INFORMED CONSENT DEFENSE

There are varying levels of informed consent, and we must decide which standard offers the most just treatment for patients and allows for the protection of autonomy. Barnhill considers arguments made by David Shaw and by Ulrik Kihlbom, which are built off of the work of Adam Kolber, regarding spectrum of involvement that patients seek. Barnhill concedes that the negatively informed consent (NIC) does allow for an increase in patient autonomy, but critiques the framework by arguing that the autonomy protected is not the autonomy of informed consent; but rather, autonomy hypothetical consent. In order for this new framework to be accepted, Barnhill believes the authors need to prove why this form of autonomy should be held supreme.

Kolber provides the groundwork for both of these positions in his paper, "A Limited Defense of Clinical Placebo Deception." In which, Kolber quotes the AMA policy identically to Barnhill, but draws conflicting conclusions. Kolber ultimately decides the AMA has an *ill advised* categorical prohibition of clinical placebo deception. Kolber works from a legal standpoint and much of his discussion follows on tort reform, survey data and his justification relies on placing the burden of proof on those desiring to implement the prohibition.

Kihlbom asserts that some patients would like a more limited role in decision-making and therefore proposes a protocol for NIC. Under this framework, a patient would be aware of only the purpose of a treatment. In such a case, a physician need only indicate, "I am recommending

X to treat your back pain, and if you would like more information, I would be happy to provide that for you." They could even continue and offer more information such as, "While the mechanism is yet to be understood, and X does not work for everyone, for the patients who do experience relief, it averages___% reduction in symptoms and there are no known side effects." If a patient would like more information, they would simply ask.

Shaw argues that this NIC standard be applied to placebo use as I describe above. Barnhill admits that this protocol would increase patient autonomy by allowing them to select the level of involvement and information they were responsible for.

In this chapter, I will analyze each of their positions independently and finally bring them together and evaluate the strength of the NIC defense.

**Kolber**

Kolber works from a legal point of view and his primary concern is to outline the dangers to physicians practicing clinical deceptive placebo use under the AMA policy, which is held to be a strict prohibition. Kolber argues the policy is over-restrictive, easy to subvert and goes against patient preferences. Barnhill's critique of Kolber is that his argument is actually protecting unexpressed patient preferences and does not actually protect patient autonomy. Given his motivation, it is hard to believe Kolber's intention is to respect patient autonomy, but rather help us to understand the danger of eliminating placebo use from the physician's toolbox. Most

importantly, Kolber proves that there is room for some deception within ethical practice. Once we accept that there is room for limited disclosure under some circumstances, it becomes easier to accept that deceptive placebo use, when preformed in line with patient preferences, and for the purpose of providing therapeutic benefit, may not be unethical.

I have already shown that the AMA doctrine should not be held to being a categorical prohibition, but let us consider Kolber's critique of a categorical prohibition. He states, "…contra the AMA, that given current knowledge of placebo effects and patient preferences, we should not categorically prohibit the deceptive use of placebos." Kolber uses the beneficence standard and continues on to say, "Deceptive placebos have genuine therapeutic benefits, and the AMA should not have prohibited them without more evidence that they are harmful." Additionally, Kolber states, "…placebo relief is, perhaps needless to say, real relief." Ultimately, Kolber holds that in order to justifiably make a categorical prohibition on deceptive placebo use, policy makers should be able to express what harms they are attempting to protect the patient from. Kolber puts forth, "…any prohibition intended to prevent the harmful consequences from the practice of deceptive placebo administration should be able to identify and characterize those consequences- something that we are currently unable to do with any precision." Throughout his discussion, Kolber continually argues that the burden of proof should be on those proponents of the policy. Essentially, we should accept clinical deceptive placebo use as just until it has been proven otherwise. To do this, Kolber recommends more research be done.

Following from this, it should not be surprising that Kolber often argues that deception does not have to be unethical or violate patient autonomy. Specifically, Kolber argues that there are occasions in which withholding information is deemed appropriate, "Even when doctors deliberately withhold knowledge from patients in order to capitalize on placebo effects, they are not necessarily deceiving them." Timing of disclosure is also relevant. As with the basket of potential treatments that the AMA doctrine appears to be providing for, permission must be given prior to the treatment. Specifically, "patients could be asked in advance to consent to deceptive placebos should they ever become suitable candidates for such treatment." Kolber warns about drawbacks to believing advanced waivers will prevent deception. First, these waivers could decrease the efficacy of all treatments received, because the patient will be aware that any of them could be a placebo. Secondly, waivers that are followed by deceptive practices are still deceptive. If we are concerned that deceptive treatments will endanger the trusting relationship between physician and patient, then even advanced warning will not necessarily prevent the patient from having negative feelings. When considering the possible drawbacks to deceptive placebo use, Kolber states, "Yet, none of these concerns demonstrates that the optimal level of therapeutic deception is zero." This leaves us believing that currently, even within the modern informed consent framework, there remains some deceptive practice. Further, this may be allowable. The distinction relies on the patients beliefs.

Once we accept that deception takes place, we must then determine if this deception should be allowable. Kolber argues that by removing deceptive placebos as a potential treatment, the AMA has limited patient autonomy and decreased their ability to choose a treatment. He argues, "…prohibition is inconsistent with the preferences of many patients." One way in which Kolber

demonstrates this is that the goals of patients are to get better. When we seek out healthcare, we are wanting to improve. Kolber acknowledges that a trusting relationship can help improve patient outcomes, but,

> "Patients do not seek out medical care in order to foster a relationship based on honesty, trust, respect and autonomous decision making. Rather, they seek medical care first and foremost to feel better. No doubt honesty, trust, respect, and autonomous decision making typically foster better patient care. If there are tradeoffs, however, between these values and successful medical outcomes, many of us would favor the later…When we evaluate the merits of beneficent deception, we are presented with difficult tradeoffs between the value of honesty and candor compared to whatever substantive benefits the deceiver attempts to convey through deception."

When asked to choose, Kolber feels that the primary concern should be improving the patients' condition. In my opinion, this point of view moves too far back to a paternalistic model. If the patient has prior consent in place, then I could accept the deception as being allowed, but I do not agree that simply stating that the benefit outweighs all other considerations is sufficient. Just as it is argued that forcing disclosure limits some patient preferences and autonomy, not allowing full disclosure and assuming the patients goal is primarily to improve also forces some patient preferences to go unmet.

However, Kolber also considers the patient preferences in a stronger justification for clinical deception. He states, "…doctors who refrain from administering deceptive placebos are imposing a particular view of treatment decision making on the patients." Essentially, by forcing practitioners to disclose everything, the medical community is not allowing patients to choose what role they play in the decision-making process. Further, there is an underlying assumption that patients are opposed to taking a placebo without consent. Kolber argues we should not readily accept this assumption because, "…it could be quite rational for patients to be open to unwittingly receiving placebos, given that placebos provide real relief from symptoms and may

also help diagnose illness." Even outside of placebo use, there are times when limited disclosure may be preferred by the patient. Kolber gives an example of Dr. T who is treating Mrs. B. In this scenario, Mrs. B has clearly stated she does not want more information, but Dr. T feels it is in her best interest, long term, to have the discussion anyway. "In this example, Dr. T acts paternalistically by revealing information that Mrs. B does not want to know…Dr. T failed, in effect to respect Mrs. B's autonomy… Had Dr. T refrained from pressing her to discuss the operation, he would have better respected her autonomy, though possibly at some cost to the overall well-being of her postoperative self." In this example, the unwanted disclose is said to decrease patient autonomy. Finally, Kolber argues, "If patients are, in fact, more willing to receive deceptive placebos than the conventional wisdom suggests, deceptive placebos may be less likely to violate patient autonomy than the conventional wisdom suggests." Barnhill critiques Kolber by stating that he is conflating autonomy with preference satisfaction. I disagree. If a patient, such as Mrs. B, expresses they do not want to discuss a treatment option further, they are making an autonomous choice. They are still actively choosing which treatment they are going to undergo, just with less disclosure. The primary concern with this defense is that there is no way to apply it to the entire medical field. There are standards in place, such as the reasonable patient standard; a standard which considers what information a reasonable patient would want to know. This obviously has the same constraints as above. No matter where you draw the line, some patients will be under-or over-informed.

Finally, we should consider how Kolber evaluates placebos. There are two classes: pure placebos and impure placebos. Impure placebos have an active agent. Kolber argues impure placebo use is far more common in the United States. When compared with pure placebos, "…they far more

frequently prescribe ordinary, active pharmaceuticals for conditions that are not pharmacologically treated by the prescribed drug." This differs from the beneficial side effects case, because the treatment in question would be prescribed for a primary complaint, which it is known to treat, but there may be the added benefit of addressing a secondary complaint. You could argue, that the treatment in question is an impure placebo for that second condition. This is certainly the case for the pseudo-placebo and steroid treatment for RA. Kolber also considers the objective perspective. Under this perspective, the effects of the treatment on the patient determine whether or not the treatment should be considered a placebo. Similarly to Barnhill, Kolber also considers what the AMA defines *specific* effect on the treatment in question.

> "Non-specific effects of placebos include the changes placebos cause by way of the patient's expectations of feeling better, selective attention to symptoms, and the conditioned responses to treatment. **While these effects likely have quite specific neurological mechanisms, the AMA probably deems them 'non-specific' because they do not proceed through the kind of pharmacological pathways that physicians and drug companies typically seek to heal patients**…There is also a growing body of neuroscientific evidence supporting the view that placebos can generate substantial pain relief that is much like the pain relief from conventional analgesics. **As noted, a number of brain imaging studies suggest that the pathways of placebo pain relief in the brain largely overlap with the pathways of pain relief from standard opioids**." (emphasis mine)

I believe Kolber is arguing that the AMA requirement of specific is too narrow, because as the placebo brain imaging studies reveal, in some cases, the placebo is working in much the same way as the active treatment. If these pathway parallels are seen between pure placebos and active agents, I believe it is far more likely to be seen with active agents being used in either the pseudo-placebo or beneficial side effects case.

The major drawback to Kolber's defense is that it is largely in consideration of what legal precedence are in place and how the AMA policy, taken as a categorical prohibition, will affect litigation. As such, Kolber is unable to provide a complete defense in the terms of respecting

patient autonomy as a primary objective. Autonomy is considered, but there is a much heavier analysis on the informed consent doctrine and what should be considered deceptive practice. Kolber also relies on beneficence generally outweighing patients' desire for a trusting relationship with the care provider. I do agree that by forcing full disclosure to 100% of patients, you will inevitably be limiting some of the patients autonomy by not allowing them to take a more passive roll in the decision making process. However, this can easily be avoided by discussing these preferences before any treatment is administered. Kolber raises concerns for advanced permission for deceptive placebo, but as these concerns are currently unmeasured, I do not believe there is enough reason to deny the waiver option to an AMA style basket of treatments. Kolber specifically considers a surgical case with Dr. T and Mrs. B. From this discussion it is clear that Kolber holds that limited disclosure should be sufficient. However, Kolber is critical of the concept of pseudo-placebo and steroid treatment of RA. He argues that physicians can articulate seemingly logical reasoning for believing the active treatments will work, despite not having proof, for almost anything. From Kolber, Kihlbom was able to begin building a protocol for negatively informed consent.

**Kihlbom**

In direct contrast to Kolber, Kihlbom's argument hinges on a trusting relationship between the patient and the physician. This is because the physician is left to decide what treatments and outcomes are in line with the patient preferences. NIC relies on a more active role by the physician and much discussion between patient and physician. While the actual methods and means of the proposed treatment are not discussed. This is not the same as true paternalism,

because the physician does discuss options with the patient and will ultimately be guided by the patients' decisions and preferences. The proposed NIC framework begins to provide room for the lack of information necessary for effective placebo use, while leaving us to believe withholding this information will not constitute deception. The major drawback to Kihlbom's defense is that it does not consider placebo directly.

Kihlbom suggests a diversion from traditional informed consent practices. Specifically, "By giving patients less information and of a different type than traditionally suggested, it is possible to secure patient autonomy with a more active role of the physician" and that we should, "relax the general practice of informed consent." In order to make this adjustment, we must accept that, "A patient may prefer that a trusted physician decide what he or she judges to be the best course of action." This shift in the informed consent framework would rely on a, "substantive patient-doctor relationship of confidence or trust." While the limited disclosure protocol may look similar in practice between Kihlbom and Kolber, the understanding of trust between the patient and physician is exactly opposite. Kihlbom assumes that this trust is necessary in order to justify relaxing the informed consent requirements and I agree. If the physician is to truly understand the patients' goals and treatment preferences open communication is required. As previously discussed, informed consent is not a one-time act. If the physician violates the patient trust, this would most likely be detrimental to all future relationships.

Once the trusting relationship has been established, we can now consider the significance of patient autonomy in regards to the decision making process. Often, informed consent and

autonomy are considered inherently linked. This is because autonomy is said to be the patients' ability to choose, or to be the direct cause, of what happens to them. Kihlbom argues you can only be the, "direct and intentional cause of what happens" if you, "understand and are aware of what is happening to you." This could be true in both the NIC and the modern informed consent frameworks. Kilhbom suggests that patients can make, "autonomous decisions with less information about the actual methods, means and risks." Essentially, a patient does not need to know how the results occur (such as the specific biochemical pathways or mechanisms of action), but rather, they simply need to be assured that there is good reason to expect that the ends will be realized. In order to do this, Kihlbom proposes the patient have, "a combination of positive and negative beliefs where the beliefs about means and methods are negative rather than positive…" There are four key components for Kihlbom's NIC protocol:

1) The patient receives information about the purpose of treatment (not means and methods)
2) It is possible to receive more information if desired
3) The treatment is voluntary (the patient must have confidence that they have a choice in treatment)
4) Consent may be withdrawn at any time (there will be no punishment for the patient changing their mind or wishing to change the treatment plan).

These tenants provide justification for all four cases: surgical consent, beneficial side effects case, pseudo-placebo and steroid treatment for RA.

In order to better illustrate his protocol, Kihlbom offers the following example,

> "…suppose I that I have a severe headache and take a couple of painkillers to get rid of it. To have sufficient understanding for acting autonomously, I surely need to have good grounds for

> believing the pills will relieve me of my headache. It seems also reasonable that I also should have well-founded negative beliefs about that taking them will not bring with them significant risks for side-effects. **However, I need no positive beliefs of how they chemically work in my brain, to have sufficient knowledge for making an autonomous decision.**" (emphasis mine)

This scenario seems reasonable for at-home or over-the-counter remedies. I would venture that most people do not consider the chemical processes before taking an Advil. The fact that I choose to do this at home, of my own free will, does not guarantee that it is permissible to apply the same lack of information to a clinical setting. Does this open the door for allowing blatant withholding of important information from the patient? Kihlbom considers this objection and resolves it by concluding, "…negative informed consent is not a question of concealing information, the information should be there if wanted." Again, I believe this requires a foundation of trust between the patient and the physician. The patient must feel comfortable and confident enough to ask for information when they are unsure.

Kihlbom's NIC protocol proposes a different starting point for disclosure. Essentially, unlike in the modern informed consent framework, the physician would start by disclosing less information. Kilhbom's framework assumes that less information may be required for the patient to make autonomous decisions about their treatments. The diagnosis, purpose and goals of the proposed treatment would all be openly discussed; however, means and methods of the proposed treatment would not be initially disclosed. The physician should actively ensure that the patient be aware that additional information would be made available upon request. I do believe that the NIC framework provides justification for all of the cases considered. The primary weakness of Kihlbom's work is that it does not consider placebo treatments specifically. Given the nature of placebo treatment, they may require specific consideration. Shaw builds off of Kihlbom's

proposed NIC framework and specifically considers placebo use. I shall evaluate his defense next.

**Shaw**

Shaw begins by outlining what is required for the NIC protocol and argues that when working within this framework, placebos can be prescribed without requiring deception. Shaw's work resolves the differences between the patient-physician relationship as outlined by Kolber and Kihlbom. Shaw concludes that as long as the symptoms are relieved, the patient need not know the treatments chemical actions. This stance highlights the importance of beneficence; as championed by Kolber, and strengthens the NIC protocol; as championed by Kihlbom.

Shaw differs from Kihlbom in that he looks specifically at how the NIC protocol can be used to ethically prescribe placebos in a clinical setting. It is important to note that the NIC protocol does not require the patient abdicate access to all information, but only to some. Shaw explains, "…(NIC), where a patient abdicates access to information to some extent, the perfect conditions exist in which placebo use is rendered ethical in the normal healthcare context: among the information that can be legitimately withheld is that the prescribed medicine is not chemically active." The normal healthcare context is that of clinical practice as opposed to research. Importantly, Shaw is stating that it is ethical to withhold the placebo nature of a treatment. Considering our test cases, if Shaw believes it is ethical to not disclose that the proposed treatment is inert, then we can comfortably assume that active substances, being issued outside of their normal use, should be covered as well. This provides some space for pseudo-placebo and for beneficial side effects case.

As opposed to Kihlbom, Shaw believes that the NIC protocol can be used in situations where the patient-physician relationship is not substantial, much like Kolber. Shaw claims, "…NIC is actually appropriate for some cases involving placebos where this relationship is not close." As long as the patient knows that they have a choice in treatment options, and further, the patient knows that they may request additional information at any time, the NIC framework can be used during any patient-physician interaction. In order to illustrate how the NIC protocol could be used in the clinical setting, Shaw provides an example,

> "Dr Jones could simply inform her patient that she is going to give him a pill that will hopefully make him feel better. This is all NIC requires…The patient simply doesn't need to know whether it is an 'active' drug or a placebo; **he knows the purpose of the treatment and that he can withdraw consent at any time**." (emphasis mine)

Shaw continues to explain that if knowing the doctor is proposing a treatment that will hopefully make them better is not sufficient, the patient only need to ask for more information. In this case then, the patient may decrease the therapeutic benefit of the placebo treatment, or may remove them as a treatment option altogether. Shaw concludes, "patients who are not satisfied with the simpler formulation above to make a specific choice between having more information and having the greatest therapeutic benefit." Shaw recognizes that there are limitations to the extent to which a patient can decline information. Specifically, that waiving the right to all information is a step too far. Similarly to Kolber, Shaw holds that the benefits of the treatment should outweigh the potential risk of deception. I do not believe beneficence alone can justify withholding information.

As argued previously, does it then follow that doctors must disclose fully to every patient? Shaw believes in doing so, physicians preclude viable treatment options and prevent the patients from

choosing a less involved role in the decision-making process. In doing so, the medical community is decreasing patient autonomy. Put another way,

> "we can only assume consent to nondisclosure of such therapeutically sensitive facts: if doctors insist on always fully disclosing information on whether drugs are active to patients, they rob themselves of the best therapeutic option and might well fins that the patient is annoyed by this. In fact, an insistence on fully informing the patient could itself violate patient's autonomy by denying them the most beneficial options."

In essence, Shaw argues that by requiring disclosure, we have denied the patient the right to autonomously choose a less informed position, or a less involved role in the decision making process. Further, we have restricted the treatment options that the patient can choose from, because with full disclosure, placebos are not as likely to be effective. Additionally, a full disclosure may not be practically viable. Consider again the surgical case. I have shown, and the literature has supported, that it is not correct to assume the patient is fully informed when consenting to surgery. As a matter of fact, it seems unreasonable to assume patients are ever fully informed. As such, the NIC framework allows for the patients to be adequately informed so that their autonomy of choice is protected. However, even if we agree that their autonomy of choice is protected, does this practice constitute deception?

Shaw concludes that NIC avoids deception. He states, "But using NIC instead of IC [informed consent] avoids this deception by having the patient agree to incomplete disclosure." Crucially, if the patient insists on more information, it will always be provided. In effect, the NIC framework shifts us from a starting part of full disclosure to partial disclosure. Kolber specifically opposes the concept of deceptive placebo waivers, because he feels secretive placebo use can still be considered deceptive, and that by acknowledging the basket of proposed treatments includes placebo, all treatments become less effective. The NIC framework does not seem to require that

placeboes be specifically consented to in advance. Therefore, we have reason to believe that the NIC framework is not deceptive and would allow for placebo treatments to achieve their optimal therapeutic affects.

**A Discussion of the Three Alternative Views**

Despite their discrepancies, when taken together the work of Kolber, Kihlbom and Shaw provide a robust defense for clinical placebo use. Kolber is perhaps the weakest of the three. He adamantly opposes "impure placebos" and while beneficial side effects case is not specifically considered, we have reason to believe Kolber would be opposed to these treatments. Specifically, Kolber is opposed to using active agents because of the added risk of negative side effects (when compared to the absence of this risk in pure placebos). Kihlbom and Shaw would both support the beneficial side effects case and the pseudo-placebo approach; whereas again Kolber may not be in support. Kolber warns that physicians can make almost any active treatment seem like it has a logical basis for treating the condition in question. For this discussion, I limited my focus to physicians who are acting in good faith to provide the best therapeutic outcome. Given this, Kolber's concern does not seem enough to deny the patient the pseudo-placebo treatments. This seems even more likely when we consider steroid use for RA. This is the standard treatment, because physicians believe there is logical reason for it to work, and patients report therapeutic benefits. According to Kolber, these treatments may not be ethical.

All three authors provide grounds for the indeterminate basket of treatments or the surgical case. They all seem to accept that there is never truly full disclosure. Once we accept that disclosure is inherently limited, we begin to consider if this limitation constitutes deception. As long as the

physicians are willing to disclose more information upon the patient's request, I do not believe that withholding information at the beginning of the treatment decision process is deceptive. All three of them provide standards for what information should standardly be disclosed. There are two main problems here.

First, Kolber and Kihlbom are discussing this issue from a perspective that does not directly apply. Kolber is considering the legal ramifications; as opposed to respecting patient autonomy form the viewpoint of an ethical practitioner. Kihlbom is not considering placebo use directly. Pervasively in the literature, the placebo nature of a proposed treatment is deemed fundamental. As such, when setting up a protocol that may allow for placebo use, it is probably best that the author discusses placebo directly-as done by Shaw.

Secondly, the literature unanimously concludes that given the individualized nature of treatment, each patient should be able to determine how much information he or she requires in order to protect their right to autonomous choice. We cannot establish a universal standard. I believe this inherent limitation on informed consent standards is a beneficial thing. Given the nature of the patient-physician relationship, the best way to respect the patient's autonomy is for continual and open communication. We should be seeking a starting point for the discussion, and I believe the NIC framework is a positive place to start. We can avoid overloading the patient (which can decrease autonomy) and we can guarantee the most options are viable for treatment (by not forcing full disclosure). By starting from a place of limited disclosure, if the patient would like to know more about the proposed treatments and alternatives, the physician may provide that information upon request. Alternatively, if we start from a position of required full disclosure,

the physician cannot move backwards to a position of less disclosure. If the patient would have preferred to make the decision from a less involved position, they now are unable to do so.

# CHAPTER V

# O'NEILL JUSTIFICATION

O'Neill's stance relies on the crucial distinction between what constitutes fully informed versus adequately informed consent. O'Neill argues what most would find a very reasonable assertion: it is not possible to give fully informed consent, because it is not possible to consent to every aspect of every possible outcome of a treatment. Patients have a limited ability to give autonomous, informed consent, and it is the care-provider's responsibility to help them. Care-providers can do this by limiting the amount of information received by the patient to only the *fundamental* aspects of actions and protocols. Given this impaired ability or capacity for autonomy, there may be a reason to hold patients' well-being paramount. However, O'Neill concludes beneficence alone is not the fundamental aim of medical practice and that there is a difference between impaired ability to offer consent and no ability to offer consent. Further, we cannot hope to have a global standard or a single boundary between what is permissible and what is deemed impermissible; but rather, we can hope to establish a way of thinking that can help us to respect patient autonomy and avoid harmful acts of paternalism.

In order to justify O'Neill's position, we must accept that there is a difference between ideal agents and how people actually are. The ideal agent is defined as rational and free, but people are not ideal. O'Neill puts forth, "…the notion that we could be 'ideal rational patients' cannot stand up to a moment's scrutiny." And further, "A contrast is often drawn between standard adult capacities for autonomy, which allow informed consent to be given and withheld, and patients' reduced capacities which demand paternalistic treatment. But patients may not be radically

different from the rest of us, in that all human capacities for autonomous action are limited." By accepting that human capacities for consent are not standard but vacillate greatly, allows us to begin to consider how actual autonomy is seen in the medical community. O'Neill concludes, "…judgments of human autonomy must be contextual, and that what it takes to respect human autonomy will vary with context." Are we to assume then to assume all aspects of autonomy and informed consent are to be determined on an individual basis and will vary per situation? I think there are nuances that will vary according to the patient's desires and capacitates, but there are some standards, which we could apply universally.

When we consider the surgical case, O'Neill provides a robust defense. She begins by asserting, "Human autonomy is limited and precarious in many contexts, and the consent given to others' actions and projects is standardly selective and incomplete." Essentially, O'Neill is claiming that all human autonomy is limited and that we are unable to consent to every aspect of the proposed action. This is true in regards to business contracts, politics and government, as well as in the medical realm. O'Neill considers surgery specifically, "When we consent we do not necessarily 'see through' to the implications of what we consent to and consent to these also. When a patient consents to an operation he or she will often be unaware of further implications or results of that which is consented to. Risks may not be understood and post-operative expectations may be vague." If then it is common for all people to give selective consent, and when consenting to an operation we accept that the patient may not fully understand all of the possible ramifications of the procedure, do we declare them uninformed? Dominant practice says yes. I believe, based on the Baylor Scott & White surgical form taken as a representative sample, the surgical case is best understood as the patient giving explicit consent to the basis of the procedure and implicit, or

tacit, consent to all of these unforeseen implications. In order to analyze the other three cases let us accept, hypothetically, that patients are limited in their capacity for giving consent and begin to work within this framework.

What will it look like to work within the limited capacity framework? O'Neill argues, "Once we focus on the limited autonomy of actual patients it becomes clear that consent to all aspects and descriptions of proposed treatment is neither possible nor required." O'Neill also states, "[patients]…understand what they can about the basics of their diagnosis and the proposed treatment, and are secure enough to refuse the treatment or to insist on a change." From here, we can reason that the AMA style basket of treatments/surgical consent is justified, and further, we can begin to build the case for beneficial side effects case, pseudo-placebo and steroid use for RA. In all of these cases, the physician would be able to explain the diagnosis to the patient. Again, we are left with a standard that is not universal. O'Neill proposes that the patients understand *what they can about the basics*, which should preclude specific physiological and/or biochemical mechanisms of the treatments, such as called for by Barnhill. At the core, O'Neill is claiming that the risks and most likely outcomes should be understood. One could argue that a patient is capable of understanding the basics of a placebo treatment, and that this may still be considered a fundamental aspect of the proposed action. This leaves us to consider if not telling the patient the placebo nature of a treatment should still be deemed deceptive.

O'Neill argues that placebo use is not deceptive. Her stance is two fold. First, she states, "Deceivers don't reveal their fundamental proposal or action." Secondly, "Use of placebos or of reassuring but inaccurate accounts of expected pain might sometimes be non-fundamental but

indispensable and so permissible deceptions." The first part of her argument applies to all of the cases we have discussed thus far. Even if the physician proposes the use of a true placebo, simply a sugar pill, they would be obliged to inform the patient of their fundamental proposal. For example, the physician could begin the conversation by telling the patient what their diagnosis is and ensuring that they understand the nature of the disease (for example, terminal, auto-immune, viral). Then, the physician could state something to the effect of, "I am recommending that you try this treatment for the purpose of relieving your back pain." If the physician is aware of clinical data showing the effectiveness of the treatment (such as decreased pain in a percentage of patients), this information could be given to help offer support, aid the patient through the decision-making process and show the caregivers' optimism or belief in the efficacy of the proposed treatment. If the patient wanted to hear other alternatives, the physician should provide them and help the patient feel that the choice is genuinely theirs. Again, the amount of information that should be provided will be determined on an individual basis. If the patient decided that they wanted to pursue a different treatment plan, the physician should then be respectful of their choice and support them through the treatment process.

Interestingly, O'Neill puts forth an argument very similar to NIC. She states, "Some find autonomous pursuit of goals more a source of frustration and anxiety than of satisfaction. In particular, many patients want relief from hard decisions and the burden of autonomy. Even when they don't want decisions to be made for them they may be unable to make them, or to make them well." And so, it may be in best practice when trying to decide whether or not the placebo nature of a proposed treatment is fundamental would be to directly ask the patient. This appears to cause a problem, because in order to receive the best benefit from placebos, the

patient shouldn't be aware that they are receiving them. However, one must remember that in modern practice, a fiduciary relationship is desired where informed consent is not a stand-alone act.

Under the fiduciary relationship framework, the first time a patient is seen in a care setting, they should indicate whether they would be willing to receive a placebo during the course of their treatment (the patient always reserves the right to change this consent at any point in treatment). The possible benefits and risks could be listed and the patient may even indicate whether they feel the placebo nature of a treatment is fundamental to their autonomous and adequately informed decision-making process. As time passed, the physician would build a trusting relationship with the patient and when the time came to offer a placebo treatment, the physician would not be required under AMA doctrine to explicitly state they were offering a placebo nor receive specific consent for the placebo. While ethical, this practice still seems not completely justified by O'Neill.

# CHAPTER VI

# CONCLUSION

In this paper, I have aimed to show that there is a pervasive misreading of the AMA doctrine within the medical ethics field. While authors, such as Barnhill and Kilhbom, take the AMA to having a stricter position in regards to the deceptive use of clinical placebo. I have shown that the AMA does not hold a categorical prohibition, but further, the AMA does not offer any justification for their position on placebo use. However, by misreading the AMA doctrine, the leading authors have begun to fill in the lacuna. By using four hypothetical test cases, I was able to evaluate these leading authors and found that none of them are without issues, but some of them are preferable. Particularly, Kolber is considering placebo use from a legal standpoint. As such, his arguments do not consider respecting patient autonomy because it is required for best ethical practice. Kihlbom proposes a useful framework with NIC, but does not consider placebo treatments directly. Considering that authors, such as Barnhill, argue that the placebo nature of a treatment must be known in order for a patient to be considered informed, Kihlbom not addressing placebos directly is a flaw. Shaw builds off of Kihlbom's work and applies the NIC framework to placebo use. In doing so, I believe Shaw provides the most robust defense for deceptive placebo use within the modern informed consent framework.

# REFERENCES


1) American Medical Association [AMA]. 2007. “America Medical Association Code of Medical Ethics, Opinion 8.083: Placebo Use In Clinical Practice.” Available at, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8083.page? (accessed 18 January 2016).

2) Baylor Scott & White Health. 2014. “Disclosure and Consent Medical and Procedures.” Online PDF. Available at, http://www.sw.org/misc/consentforms/pdf/8000/8783B-BSWH.pdf (accessed 10 April 2016)

3) Bostick, Nathan A, Robert Sade, and Mark A (& others) Levine. "Placebo Use In Clinical Practice: Report Of The American Medical Association Council On Ethical And Judicial Affairs." *Journal Of Clinical Ethics* 19.1 (2008): 58-61. *Philosopher's Index*. Web. 18 Jan. 2016.

4) Barnhill, Anne. "What It Takes To Defend Deceptive Placebo Use." *Kennedy Institute Of Ethics Journal* 3 (2011): 219. *Project MUSE*. Web. 18 Jan. 2016.

5) Boyd, Kenneth. "The Impossibility Of Informed Consent?." *Journal Of Medical Ethics: The Journal Of The Institute Of Medical Ethics* 41.1 (2015): 44-47. *Philosopher's Index*. Web. 18 Jan. 2016.

6) Kihlbom, Ulrick. "Autonomy and Negatively Informed Consent." *Journal of Medical Ethics* 2008: 146. *JSTOR Journals*. Web. 18 Jan. 2016.

7) Kolber, Adam J. "Limited Defense Of Clinical Placebo Deception, A [Article]." Yale Law & Policy Review 1 (2007): 75. HeinOnline. Web. 24 Jan. 2016.

8) Levy, Neil. "Forced To Be Free? Increasing Patient Autonomy By Constraining It." *Journal Of Medical Ethics* 40.5 (2014): 293-300. *MEDLINE Complete*. Web. 18 Jan. 2016.

9) O'Neill, Onora. "Paternalism And Partial Autonomy." *Journal Of Medical Ethics* 10.4 (1984): 173-178. *MEDLINE Complete*. Web. 18 Jan. 2016.

10) Salgo V (1957) Leland Stanford Jr. Univ. Bd. Trustees. 154 Cal. App. 2d 560, 317 P.2d 170.

11) Shaw, David. "Prescribing Placebos Ethically: The Appeal of Negatively Informed Consent." *Journal of Medical Ethics* 2009: 97. *JSTOR Journals*. Web. 18 Jan. 2016.